

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
STATESVILLE DIVISION  
CASE NOS. 5:15cv57-RLV; 3:15CV211-RLV**

<b>ROMONA WINEBARGER,</b>	)
<b>And REX WINEBARGER,</b>	)
<b>Plaintiffs,</b>	)
	)
<b>v.</b>	)
	)
<b>BOSTON SCIENTIFIC</b>	)
<b>CORPORATION,</b>	)
<b>Defendant.</b>	)

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<b>MARTHA CARLSON,</b>	)
<b>Plaintiffs,</b>	)
	)
<b>v.</b>	)
	)
<b>BOSTON SCIENTIFIC</b>	)
<b>CORPORATION,</b>	)
<b>Defendant.</b>	)

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**DEFENDANT BOSTON SCIENTIFIC CORPORATION'S OBJECTIONS  
TO PLAINTIFFS' COUNTER DESIGNATIONS AND EXHIBITS  
TO DEFENDANT'S COUNTER DESIGNATIONS**

Defendant Boston Scientific Corporation ("Boston Scientific") hereby submits its objections to Plaintiffs' counter designations and exhibits to Defendant's counter designations for the above-referenced cases. Boston Scientific incorporates by reference its objections and counter designations to any exhibits and/or testimony previously designated by Plaintiffs in this matter. Boston Scientific reserves the right to amend, supplement, or withdraw its designations at any time before or during trial. Furthermore, Boston Scientific reserves the right to amend, supplement, or withdraw its designations subject to the Court's rulings on evidentiary matters in

the above-referenced cases including, but not limited to, motions *in limine*. Boston Scientific also reserves the right to object to any documents or testimony that Plaintiffs may offer at trial.

### **GENERAL OBJECTIONS**

**OBJECTION NO. 1:** Boston Scientific generally objects to Plaintiffs designating testimony from regulatory affairs witnesses Michelle Berry and Robert Miragliuolo while – at the same time – objecting to any evidence regarding regulatory background and references to the FDA.<sup>1</sup> Without the appropriate regulatory context, specifically evidence relating to Boston Scientific’s interactions and communications with the FDA, Plaintiffs’ designations from regulatory affairs witnesses are misleading, confusing, and unduly prejudicial under Fed. R. Evid. 403.

**OBJECTION NO. 2:** Boston Scientific generally objects to Plaintiffs’ use of deposition testimony and exhibits regarding the medical application caution statement contained in the Marlex Material Safety Data Sheet ("MSDS") on grounds that it is irrelevant, unduly prejudicial, misleading, and will cause confusion under Fed. R. Evid. 401, 402, and 403. Notwithstanding these objections, if the Court admits evidence regarding the medical application caution statement contained in the MSDS, the Court should also permit Boston Scientific to offer into evidence its communications with the FDA regarding the medical application caution statement at issue in this litigation.

**OBJECTION NO. 3:** Boston Scientific generally objects to Plaintiffs’ designation of failure to warn testimony because it will be irrelevant and unduly prejudicial as to the *Carlson* Case. Because all failure to warn evidence is irrelevant to Ms. Carlson’s case, any evidence that Ms. Winebarger wishes to present on the adequacy of Boston Scientific’s warnings or Boston Scientific’s alleged negligence in creating those warnings will be irrelevant and misleading to

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<sup>1</sup> See, e.g., (DE No. 141 at 3).

jurors who must render a verdict only on Ms. Carlson's design defect and other surviving claims.<sup>2</sup> Accordingly, Boston Scientific objects to all failure to warn evidence on grounds that it is irrelevant, misleading, confusing, and unduly prejudicial under Fed. R. Evid. 401, 402, and 403.

**OBJECTION NO. 4:** Boston Scientific generally objects to Plaintiffs' use of testimony from Dr. Mathew Davies' deposition on December 29, 2014, because testimony from Dr. Davies was not previously designated by any party in this action and falls outside the scope of any issue raised by Boston Scientific in its deposition designations. For these reasons, Boston Scientific generally objects to Plaintiffs' proffered designations from Dr. Mathew Davies' deposition on December 29, 2014.

### **OBJECTIONS**

<b>Defendant's Objections to Plaintiffs' Counter Designations of Michelle Berry</b>		
<b>Date of Deposition</b>	<b>Disputed Testimony</b>	<b>Basis for Defendant's Objection</b>
12/13/13	76:3-21	Object to Exhibit 75 as: Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	77:8-78:4	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.

<sup>2</sup> For further discussion on this issue, see (DE No. 133 at 12-14).

	79:20-80:1	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	80:3-13	Object to Exhibit 76 as: Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	81:13-82:1	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	83:5-84:4	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	85:4-7	Object to Exhibit 77 as: Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.

	85:15-24	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs
	86:20-87:20	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	88:22-92:13	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	92:14-23	Completeness Objection (106): Add 92:14-23 to testimony 92:2-9.
	96:11-18	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	97:7-11	Object to Exhibit 78 as: Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.

	97:15-23	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	98:6-20	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	100:12-101-12	Object to Exhibit 79 as: Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Needlessly cumulative (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	101:11-12	Object to Exhibit 80 as: Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	107:11-108:6	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.

	120:22-121:5	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
	182:7-12	Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403).
	183:13-14	Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), implicates BSC financial information
Boston Scientific objects to the use of Exhibits 75, 76, 77, 78 79, and 80, which are included in Plaintiffs' designated deposition testimony of Michelle Berry.		

<b>Defendant's Objections to Plaintiffs' Counter Designations of Evan Brasington</b>		
<b>Date of Deposition</b>	<b>Disputed Testimony</b>	<b>Basis for Defendant's Objection</b>
8/13/13	193:15-19	Irrelevant 401/402, Cause confusion (403), Unduly prejudicial (403)
	203:12-204:22	Outside scope of previous BSC designations, Misleading (403), Cause confusion (403), Unduly prejudicial (403).

<b>Defendant's Objections to Plaintiffs' Counter Designations of Janice Connor</b>		
<b>Date of Deposition</b>	<b>Disputed Testimony</b>	<b>Basis for Defendant's Objection</b>
8/13/13	153:15-18	Outside scope of previous BSC designations, Implicates foreign regulatory action, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation, Implicates complication not experienced by Plaintiffs.
8/14/13	370:11-20	Outside scope of previous BSC designations, Irrelevant (401/402), Unduly prejudicial (403), Cause confusion (403), Implicates complications not experienced by Plaintiffs.
	377:13-16	Irrelevant (401/402), Unduly prejudicial (403), Cause confusion (403), Implicates complications not experienced by Plaintiffs.
	379:1-13	Irrelevant (401/402), Unduly prejudicial (403), Cause confusion (403), Implicates complications not experienced by Plaintiffs.
3/11/15	150:3-7	Outside scope of previous designations, Inadmissible for reasons discussed in BSC MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Complication not experienced by Plaintiffs.
	154:19-155:6	Outside scope of previous designations, Inadmissible for reasons discussed in Boston Scientific's MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates complication not experienced by Plaintiffs.
4/21/15	656:3-660:11	Irrelevant (401/402) (fact medical organizations have adopted statements is relevant but e-mail surrounding its generation is not), Cause confusion (403), Misleading (403), Unduly Prejudicial (403)
	661:14-664:23	Object to Exhibit 1352 as: Outside scope of previous designations, Inadmissible for reasons discussed in BSC MILs, Irrelevant (401/402), Misleading (403), Cause confusion (403), Unduly prejudicial (403), Implicates product not at issue in this litigation.
Boston Scientific objects to the use of Exhibit 1352, which is included in Plaintiffs' designated deposition testimony of Janice Connor.		

<b>Defendant's Objections to Plaintiffs' Counter Designations of Mathew Davies, M.D.</b>		
<b>Date of Deposition</b>	<b>Disputed Testimony</b>	<b>Basis for Defendant's Objection</b>
12/29/14	9:13-15	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations.
	102:23-103:9	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	144:13-20	Object to Exhibit 14 as: Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	151:10-154:11	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	192:17-22	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.

<b>Defendant's Objections to Plaintiffs' Counter Designations of Mathew Davies, M.D.</b>		
	193:20-194:18	Object to Exhibit 17 as: Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	195:2-17	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	198:10-12	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	199:5-200:1	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	202:8-20	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.

<b>Defendant's Objections to Plaintiffs' Counter Designations of Mathew Davies, M.D.</b>		
	203:20-204:20	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation
	205:9-17	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	208:18-210:4	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	210:12-211:8	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Calls for speculation, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation
	219:7-23	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.

<b>Defendant's Objections to Plaintiffs' Counter Designations of Mathew Davies, M.D.</b>		
	221:16-222:5	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	226:12-22	Object to Exhibit 18 as: Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation
	227:11-230:12	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	230:13- 233:11	Completeness Objection (106): add testimony 230:13- 233:11 to designation 227:11 - 230:12
	233:12-234:3	Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	240:9-241:6	Object to Exhibit 20 as: Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.

<b>Defendant's Objections to Plaintiffs' Counter Designations of Mathew Davies, M.D.</b>		
	258:3-6	Object to Exhibits 21 and 22 as: Outside the scope of previous BSC designations, witness was not identified in either party's affirmative designations or counter designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403) Inadmissible for reasons discussed in Boston Scientific's MILs, Implicates product not at issue in this litigation.
	258:7-13	Completeness objection (106): add testimony 258:7-13 to designation 258:3-6
Boston Scientific objects to the use of Exhibits 14, 17, 18, 20, 21, and 22, which are included in Plaintiffs' designated deposition testimony of Mathew Davies.		

<b>Defendant's Objections to Plaintiffs' Counter Designations of James Goddard.</b>		
<b>Date of Deposition</b>	<b>Disputed Testimony</b>	<b>Basis for Defendant's Objection</b>
3/29/13	395:16-23	Object to Exhibit 61 as: Outside the scope of previous BSC designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403)
	398:23-399:3	Outside the scope of previous BSC designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403)
	399:8-21	Outside the scope of previous BSC designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403)
	547:20-550:5	Outside the scope of previous BSC designations, Irrelevant (401/402), Misleading (403), Unduly Prejudicial (403), Cause Confusion (403)
Boston Scientific objects to the use of Exhibit 61, which is included in Plaintiffs' designated deposition testimony of James Goddard.		

Defendant's Objections to Plaintiffs' Counter Designations of Robert Miragliuolo		
Date of Deposition	Disputed Testimony	Basis for Defendant's Objection
4/25/13	502:17-23	Irrelevant (401/402), Cause confusion (403), Unduly prejudicial (403), Misleading (403), Inadmissible for reasons stated in BSC MILs, Implicates complication not experienced by Plaintiffs.

Defendant's Objections to Plaintiffs' Counter Designations of Charles Smith		
Date of Deposition	Disputed Testimony	Basis for Defendant's Objection
1/11/14	43:23-44:4	Irrelevant (401/402), Inadmissible for reasons stated in BSC MILs, Unduly prejudicial (403).

Dated: 08/04/2015

Respectfully submitted,

s/ Leslie C. Packer  
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**CERTIFICATE OF SERVICE**

I hereby certify that on August 4, 2015, I caused the foregoing document to be electronically filed with the Clerk of the court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive services in this matter.

s/ Leslie C. Packer  
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